DMB

12-7-99

12-8-99

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4910]

Draft Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #3; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ‘ ‘Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #3.’ ’ This draft guidance document is intended to assist facilities and their personnel to implement the Mammography Quality Standards Act of 1992 (the MQSA).

DATES: Written comments concerning this draft guidance must be received by *(insert date 90 days after date of publication in the* **Federal Register).**

ADDRESSES: Submit written requests for single copies on a 3.5’ diskette of the draft guidance document entitled “Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document # 3” to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. **See** the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

ch9982

NAD 1

FOR FURTHER INFORMATION CONTACT: Charles A. Finder, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3332.

SUPPLEMENTARY INFORMATION:

I. Background

The MQSA was passed on October 27, 1992, to establish national quality standards for mammography. After October 1, 1994, the MQSA required all mammography facilities, except facilities of the U.S. Department of Veterans Affairs, to be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary). The authority to approve accreditation bodies and to certify facilities was delegated to FDA by the Secretary to FDA. On October 28, 1997, FDA published the MQSA final regulations in the **Federal Register.** The final regulations became effective April 28, 1999, and replaced the interim regulations (58 FR 67558 and 58 FR 67565). Development of this draft guidance document began in March 1999.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on the final regulations implementing the MQSA. The draft guidance is not final nor is it in effect at this time. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive "Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #3'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1496) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH Home Page includes ' 'Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document # 3," device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, "Mammography Matters," and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. "Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document # 3" will be available at http://www.fda.gov/cdrh/mammography.

IV. Comments

Interested persons may, on or before *(insert date 90 days from date of publication in the* **Federal Register),** submit to Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except that

individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 11/24/99
November 24, 1999

Linda S. Kahan

Linda S. Kahan
Deputy Director for
Regulations Policy
Center for Devices and
Radiological Health

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL
Jan Windsor

[FR Doc. 99–???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F